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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER HUNNICUTT, RACHEL KAPUST				
ART UNIT		PAPER NUMBER		
1647				

DATE MAILED: 12/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/017,479

Applicant(s)

REENAN ET AL.

Examiner

Rachel K. Hunnicutt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-32, 53, 54, 56, 58, 59, 61-71, 73, 75-80 and 82-103 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31, 53, 54, 58, 59, 61-71, 73, 75-80 and 82-103 is/are rejected.
- 7) ☒ Claim(s) 32 and 56 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

RESPONSE TO AMENDMENT

Applicant's amendment filed September 20, 2004 is acknowledged. Claims 1-30, 33-52, 55, 57, 60, 72, 74, and 81 have been canceled. Claims 53, 54, 56, 58, 61, 67-71, 73, 75, 83-86, and 95 are amended. Claims 31, 32, 53, 54, 56, 58, 59, 61-71, 73, 75-80, and 82-103 are under consideration. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claim Rejections/Objections Withdrawn

The rejection of claims 53, 54, 56, 58, 59, 61-71, 73, 75-80, and 83-103 under 35 U.S.C. 112, second paragraph, regarding the term "evaluate" is withdrawn in response to Applicant's amendments to the claims.

The rejection of claims 68-71 under 35 U.S.C. 112, second paragraph, regarding the term "test molecule" is withdrawn in response to Applicant's amendments to the claims.

The rejection of claims 69 and 70 under 35 U.S.C. 112, second paragraph, regarding the relationship of the steps of claims 69 and 70 to the method of claim 68, is withdrawn in response to Applicant's amendments to the claims.

The rejection of claim 71 under 35 U.S.C. 112, second paragraph, regarding the relationship of the step of claim 71 to the method of claim 68, is withdrawn in response to Applicant's amendments to the claim.

The rejection of claims 73 and 75-80 under 35 U.S.C. 112, second paragraph, regarding cells that "can" express a transporter polypeptide, is withdrawn in response to Applicant's amendments to the claims.

Claim Rejections Maintained/New Grounds of Rejection

The rejection of claims 53, 59, 64-71, 83, and 84 under 35 U.S.C. 112, second paragraph, is maintained for reasons of record on p. 3 of the office action of paper no. 0404. Claims 53, 59, and 64-67 are now drawn to detecting an “activity-modulating interaction”. This limitation is still vague and indefinite. One skilled in the art would not be able to read the claims and know whether or not they were practicing the claimed invention. It appears that Applicants are intending to claim binding assays or assays which screen for modulators of transport activity of SEQ ID NO: 2. The claims are missing steps which detail what is being measured. For example, claim 53 reads “a method to assess interaction of a test molecule with a transporter polypeptide” by “detecting interaction of the test molecule with the transporter polypeptide, wherein the interaction is a binding interaction or an activity-modulating interaction”. What does the activity-modulating interaction indicate? Is the test molecule an inhibitor, an antagonist, an agonist? The claims need to be amended so that they clearly detail the methods being claimed.

The rejection of claims 67, 71, and 83-103 under 35 U.S.C. 112, second paragraph, is maintained for reasons of record p. 5 of the office action of paper no. 0404. Claims 67, 71, and 83-103 have been amended so that they are drawn to methods of “detecting rate of aging”, however the specification does not define what is being measured by measuring the rate of aging. The specification teaches that increased life span is a measurable indication of aging, yet the claims potentially encompass far more than increased life span. For instance, free radical damage in a cell is a symptom of aging, yet one of skill in the art would not know whether such a method is meant to be encompassed by the claims. The rejection could be obviated by amending the claims to read “measuring the life span of the cell” so long as there is written support for the amendment in the specification.

Claims 31, 53, 54, 58, 61-63, 67-71, 82-94, and 103 are newly rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: having the

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polypeptide be expressed in a cell. Claims 31, 61-63, and 82 encompass measuring the amount of carboxylate that is transported, however the claims fail to explain the presence of the carboxylate. Similarly, claims 53, 54, 58, 66-71, 83-94, and 103 encompass measuring transporter activity of SEQ ID NO: 2, but the claims lack the steps explaining how transporter activity is going to be measured outside of the cell. These rejections could be obviated by amending the claims such that the transporter polypeptide is expressed in a cell.

Claims 73 and 75-80 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 73, as amended, reads "a method to assess a cell". The method is drawn to detecting expression of mRNA which encodes SEQ ID NO: 2. Similarly, claim 75, as amended, is drawn to a method "to assess a cell," wherein "transporter activity" of the cell is detected. The methods are missing an essential method step, because the methods do not teach how the cell is being assessed. Applicants do not teach what is being measured. In addition, the nucleic acid encoding SEQ ID NO: 2 must have a promoter to allow for generation of mRNA. Also, the limitation of "providing a cell that contains a nucleic acid encoding a transporter" allows for both DNA and mRNA. If Applicants intend for it to be mRNA, it would be indistinguishable from the mRNA being measured in the last step of the claim. The claims are also missing steps which indicate what an increase or decrease in expression of mRNA represents. In addition, claim 75 is drawn to "detecting a transporter-activity of the cell". The activity is not of the cell, but rather of the polypeptide comprising SEQ ID NO: 2. The claim should be amended to reflect that the activity is of the transporter polypeptide that comprises SEQ ID NO: 2.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 53, 59, and 64-67 are newly rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for measuring the transport activity of a

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polypeptide comprising SEQ ID NO: 2, does not reasonably provide enablement for measuring any activity-modulating interaction. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue include, but are not limited to: 1) nature of the invention; 2) state of the prior art; 3) relative skill of those in the art; 4) level of predictability in the art; 5) existence of working examples; 6) breadth of claims; 7) amount of direction or guidance by the inventor; and 8) quantity of experimentation needed to make and/or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Claims 53, 59, and 64-67 are drawn to measuring activity-modulating interactions. Applicants teach that the polypeptide comprising SEQ ID NO: 2 is a carboxylate transporter (p. 2 of specification). Applicants have also taught that mutations within the gene encoding SEQ ID NO: 2 cause an increase in the life span of *Drosophila*, both in live flies and cells in culture (p. 7 of specification). These are the only functions taught to be associated with a polypeptide comprising SEQ ID NO: 2. One skilled in the art would not know what else could be measured that would be an indication of an “activity-modulating interaction”. The specification does not provide any guidance as to other activities which could be measured in “activity-modulating interactions”. The specification is only enabling for measuring carboxylate transportation and for measuring *Drosophila* cell and/or fly life span.

Conclusion

Claims 32 and 56 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 31, 53-54, 58-59, 61-71, 73, 75-80, and 82-103 are rejected.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel K. Hunnicutt whose telephone number is (571) 272-0886. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RKH
12/2/04


JANET ANDRES
PRIMARY EXAMINER